

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: DIGITEK PRODUCTS  
LIABILITY LITIGATION

MDL No. 1968

THIS DOCUMENT RELATES TO ALL CASES

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**PRETRIAL ORDER #13  
(Preservation Order - Digitek® Information)**

Based upon the stipulation and agreement by the parties, it is hereby **ORDERED** as follows:

1. That any and all preservation orders entered by any transferor court before the filing of this Court's Pretrial Order #1 ("PTO #1"), and any and all preservation obligations imposed by any such prior preservation orders, are replaced and supplanted by this Order. As such, this Order modifies and replaces paragraphs 8 and 15 of PTO #1. The parties acknowledge that their duty to preserve discoverable and relevant or potentially relevant information, as defined in Paragraphs 3 and 9 of this Order and Rule 26 of the Federal Rules of Civil Procedure, arose prior to entry of this Order. The parties also acknowledge that the terms of this Order shall govern their preservation obligations in this matter unless and until this Order is modified, and that any preservation obligations arising subsequent to this Order in any court in any other jurisdiction will not abrogate or reduce any of the preservation obligations set forth in this Order.

2. Pursuant to the Federal Rules of Civil Procedure and this Order, all parties and their counsel will continue to take reasonable steps to preserve evidence that may be discoverable or relevant to this action, as defined in Paragraphs 3 and 9 of this Order.

3. Generally, this action involves the sale and recall of the pharmaceutical digoxin sold under the trade name Digitek®. Plaintiffs allege that some of the product sold under that trade name was defective in that it may have contained an incorrect dosage of digoxin, the active ingredient in the product. As a result some Plaintiffs claim physical injury, some claim economic damages, and some claim both physical injury and economic damages. Accordingly, “relevant” or “potentially relevant” documents and/or tangible things, as used in this Order, whether in the possession, custody, or control of any Defendant(s) or any Plaintiff(s), are those documents and/or tangible things that pertain to the manufacturing, distribution, marketing, sales, and recall of Digitek® before it left the Defendants’ control and after it was returned by any distributor, wholesaler, pharmacy, health care provider, or end consumer; documents reflecting any monies paid by any Plaintiff to purchase the product; prescription, pharmacy, and medical records reflecting the prescription, purchase, or sale of Digitek® or digoxin; documents and/or any notes prepared by any individual Plaintiff which relate to any alleged injuries; any research any Plaintiff may have undertaken to determine the source or cause of his/her injury or to investigate his/her claim; and any documents which support a Plaintiff’s claim of injury or damages. Because Digitek® is still being returned to Defendants pursuant to the recall, documents created after the date of this Order may also have to be preserved if they relate to the recall effort or document a Plaintiff’s attempt to return any unused Digitek®.

4. This Order imposes no obligation on the parties, beyond what might be required by applicable regulatory requirements or document retention policies, to preserve any Electronically Stored Information (“ESI”), documents, or tangible things other than discoverable information and relevant or potentially relevant documents and information, as defined in Paragraphs 3 and 9 of this Order. Nothing in this Order prohibits Plaintiffs or Defendants from

subsequently seeking additional preservation of information beyond what is required by this Order or from moving the Court for an Order imposing additional preservation obligations; provided, however, that any such new or supplemental preservation obligations will attach and apply only as of the date of any such supplemental Preservation Order and going forward from that date.

**Defendants' Obligations**

5. Except as otherwise limited in this Order, Defendants have an obligation to preserve potentially relevant ESI, potentially relevant hard copy documents, and potentially relevant tangible things which were created at any time after January 1, 1998 and before August 1, 2008, except that documents created after July 31, 2008 that relate to the recall effort or document a Plaintiff's attempt to return any unused Digitek® also must be preserved.

6. Defendants are pharmaceutical companies that continue to manufacture necessary pharmaceutical products unrelated to these proceedings. The Court is aware that many of the IT systems utilized by pharmaceutical companies are highly specialized and that there are certain limitations intrinsic to certain operating systems and hardware that may make it overly burdensome or impossible to preserve every type of electronic file.

7. Therefore, this Preservation Order strikes a balance between achieving the goals of preserving relevant documents and ESI through reasonable measures and means, without imposing unreasonable costs and/or burdens on a Party responding to production requests, and allowing Defendants to continue to run their specialized programs and databases so as to allow Defendants' computer environment to effectively and efficiently support and sustain their operations without risking the introduction of error into the process.

8. Accordingly, the Court finds that the preservation activities set forth below satisfy Defendants' preservation obligations in this matter and orders Defendants to take the following measures to preserve information:

- a. Provide individuals who possess or may possess potentially relevant ESI or documents with a Litigation Hold Notice ("Hold Notice"), ordering them to preserve any such ESI or documents. This Hold Notice shall instruct the custodians to preserve any relevant ESI or physical documents (such as paper), as well as potentially relevant ESI or documents, whether kept on computer networks, removable media, databases, email, or local hard drives, and relevant tangible things;
- b. On a regular basis, provide those who received Hold Notices with a renewed notice of the continuing obligation to preserve such ESI, documents, or materials;
- c. Preserve the contents of the hard drives of those individuals who may reasonably possess potentially relevant ESI or documents. This obligation does not require subsequent copies of any hard drive of any individual that was/is preserved after June 1, 2008;
- d. Preserve emails by (1) disabling the automatic email deletion setting for the emails of relevant custodians and (2) extending, until the close of discovery, the time period during which email may be recovered if deleted by any custodian or suspending the ability of custodians to purge their deleted items folder, depending upon the type of email system utilized by the Defendant. Subject to the provisions of Paragraph 8g of this Order, taking these steps or utilizing an archive server will obviate the need to preserve backup tapes of the email servers made after these steps were taken by a Defendant;

e. Preserve relevant or potentially relevant information stored on any removable media such as USB hard drives; removable “thumb drives”; and/or mobile devices such as “pocket PCs” or “blackberry” devices;

f. The Court recognizes that relevant information may be stored in databases which, to operate properly, must be allowed to change as records are updated to reflect transactions or processes in the manufacture, sale, and distribution of pharmaceutical products. Concerning these databases, Defendants shall ensure that any portion of any database(s) containing relevant or potentially relevant ESI has an audit trail or audit tracing that allows the database owner to roll back any transaction and record the date, prior value, and the user identification of the person who made any changes, and that such audit trail or audit tracing is currently in effect and enabled. Because of Defendants’ enabling of the audit trail or audit tracing function of the database(s), no additional backup of the database(s) is required beyond Defendants’ preservation of backup tapes as set forth in Paragraph 8g of this Order;

g. Preserve a full set of file, application, database, and email backup tapes taken at or near the end of July, 2008. No backup tapes created after this set of backup tapes need be preserved and any such subsequent backup tapes may be recycled by Defendants in the ordinary course of their applicable policy;

h. Instruct custodians of any relevant or potentially relevant ESI that (1) would otherwise be deleted under a Defendant’s document retention program or (2) is contained within a shared electronic file location, to ensure that the ESI will be preserved and will not be subject to being deleted or overwritten. Defendants also may, at their discretion, extract all such information and store it in a secure location;

i. Defendants are not required to prevent deletion or otherwise preserve and retain temporary files;

j. Make their best efforts to preserve the substance of voice mail messages.

Defendants need not retain voice mail messages in their native application if Defendants determine that doing so is not practicable. Defendants may preserve relevant voice mail messages by exporting the messages to a format which would be usable by the Plaintiffs, e.g., wave format, or by creating a transcription of the voice mails or forwarding the message to an email server through unified messaging to the extent such a system exists;

k. Act reasonably to preserve potentially relevant hard copy and physical materials and/or tangible things, including any and all videos and audio/visual recordings concerning the manufacturing, sale, marketing, development, distribution, and recall of Digitek®, and all Digitek® tablets, labels, bottles, vials, containers, or packaging of any kind.

#### **Plaintiffs' Obligations**

9. Except as otherwise limited in this Order, Plaintiffs have an obligation to preserve potentially relevant ESI, potentially relevant hard copy documents, and potentially relevant tangible things which were created at any time after January 1, 1998. This includes: documents or data relating to their prescription, purchase, and use of Digitek®; documents relating to their use of pharmacies; documents relating to their medical history, including but not limited to documents relating to any injuries they may claim resulted from exposure to Digitek®; any information they may have secured concerning both the Digitek® recall and their investigation of any claim they may have against any of the Defendants; and any communications they may have with any individual(s) concerning their alleged injuries or claims.

10. This Order generally contemplates that a Plaintiff's personal computing environment, to the extent it exists, consists of one or more "stand-alone" personal computers. If, however, for some reason a Plaintiff has a personal computing environment which is more complex, then the Plaintiff has an obligation to ensure preservation of potentially relevant information in a manner consistent with Defendants' obligations.

11. Plaintiffs' duty to preserve ESI extends to the preservation of any relevant or potentially relevant information on any computer owned by a Plaintiff's employer(s) which was used by the Plaintiff to create, transmit, or receive any personal information at any time since January 1, 1998. Likewise, to the extent Plaintiffs have potentially relevant paper or electronic documents at their place of employment, Plaintiffs have a duty to arrange for the preservation of such documents and/or information and notify Defendants of its existence.

12. Plaintiffs may also have potentially relevant voice mail messages and the Court is aware that many home voice mail systems are limited in how many messages may be stored.

13. Accordingly, the Court finds that the preservation activities set forth below satisfy Plaintiffs' preservation obligations in this matter and orders Plaintiffs to take the following measures to preserve information:

a. Plaintiffs' respective counsel shall provide their client(s), and any individual under their client's control who possesses or may possess potentially relevant ESI, documents, or materials, with a Hold Notice, ordering them to preserve any such ESI, documents, and/or materials. This Hold Notice must instruct recipients to preserve physical documents (such as paper) as well as potentially relevant ESI or materials, whether kept on computer networks, removable media, databases, email, or local hard drives, and relevant tangible things;

b. Plaintiffs' respective counsel shall remind, on a regular basis, their client(s) of the continuing obligation to preserve;

c. Preserve all potentially relevant tangible things in their possession, including, but not limited to, all Digitek® tablets and any Digitek® labels, bottles, vials, containers, or packaging of any kind;

d. Preserve the contents of the hard drives of those Plaintiffs, or those under their control, who may reasonably possess potentially relevant ESI or documents. This obligation does not require subsequent copies of hard drives, if copied, for preservation purposes;

e. Preserve potentially relevant information stored on any removable media such as USB hard drives; removable "thumb drives"; and/or mobile devices such as "pocket PCs" or "blackberry" devices;

f. Preserve any newly created potentially relevant ESI or documents;

g. Make their best efforts to preserve the substance of potentially relevant voice mail messages. Plaintiffs need not retain voice mail messages in their native application if Plaintiffs determine that doing so is not practicable. Examples of acceptable preservation would be recording to a magnetic tape; exporting the message to a wave file; or forwarding the message to an email server through unified messaging to the extent such a system exists;

h. Preserve potentially relevant email (whether on a personal or home computer or on a "work" computer owned by a third party) and disable the automatic deletion setting for emails to prevent destruction of any potentially relevant emails. If disabling the automatic deletion function is beyond the control or ability of the Plaintiff, then Plaintiff must notify his or her counsel of this issue and identify the owner of the computer or server containing

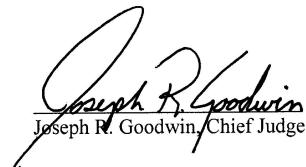
potentially relevant ESI and Plaintiff's Counsel must so notify Defendants' Counsel promptly to advise of the potential for destruction of such ESI. Defendants may also take reasonable efforts to obtain the potentially relevant email as necessary; and

i. Act reasonably to preserve potentially relevant hard copy and physical materials, including any and all videos and audio/visual recordings concerning the claims in this litigation and/or concerning the manufacturing, sale, promotion, marketing, distribution, and recall of Digitek®.

14. Nothing in this Preservation Order in any way alters Defendants' or Plaintiffs' obligations to produce ESI or requires Defendants or Plaintiffs to produce ESI that is inaccessible.

The court **DIRECTS** the Clerk to file a copy of this order in 2-08-md-1968 which shall apply to each member Digitek-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2-09-cv-0116. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at [www.wvsd.uscourts.gov](http://www.wvsd.uscourts.gov).

ENTER: February 11, 2009



Joseph R. Goodwin  
Joseph R. Goodwin, Chief Judge

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